

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA and :  
NEW YORK STATE, ex rel. :  
IRINA GELMAN, DPM, :

Plaintiffs, :

vs. :

GLENN J. DONOVAN, DPM, NEW :  
YORK CITY HEALTH and HOSPITALS :  
CORPORATION and PHYSICIAN :  
AFFILIATE GROUP OF :  
NEW YORK, P.C., :

Defendants. :

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**RELATOR'S MEMORANDUM OF LAW IN OPPOSITION  
TO DEFENDANTS' MOTION TO DISMISS**

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FARRELL FRITZ, P.C.  
Kevin P. Mulry, Esq.  
1320 RXR Plaza  
Uniondale, New York 11556-1320  
Tel. (516) 227-0620

KAISER LAW FIRM, PLLC  
Geoffrey R. Kaiser, Esq.  
926 RXR Plaza  
Uniondale, New York 11556-0926  
Tel. (516) 570-3071

WEISS, ZARETT, BROFMAN &  
SONNENKLAR, P.C.  
David A. Zarett, Esq.  
3333 New Hyde Park Rd., Suite 211  
New Hyde Park, New York 11042  
Tel: (516) 627-7000

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Relator Irina Gelman (“Relator”) respectfully submits this Memorandum of Law in opposition to the motion of Defendants Glenn J. Donovan, DPM (“Donovan”), New York City Health and Hospitals Corporation (“HHC”) and Physician Affiliate Group of New York, P.C. (“PAGNY”) (collectively, “Defendants”) to dismiss the First Amended Complaint (“FAC”) pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6).

### **PRELIMINARY STATEMENT**

In this case, Relator alleges that fraud permeated the Podiatric Medicine and Surgery Residency Program (“PMSR Program”) at Coney Island Hospital (“CIH”). Relator alleges that podiatric residents were unsupervised, certain residents were unpermitted and could not lawfully treat patients, medical records were altered and falsified, and PMSR Program policies were virtually nonexistent. Relator alleges that Defendants fraudulently billed Medicare and Medicaid for non-reimbursable teaching physician services, hospital services incorporating non-reimbursable podiatry resident services, and Graduate Medical Education (“GME”) costs associated with a fraudulent PMSR Program. As alleged in the FAC, the PMSR Program itself failed to meet the requirements of the Council on Podiatric Medical Education (“CPME”), and the presentation of cost reports for GME reimbursement to Medicare and Medicaid without disclosing pervasive program fraud and other core deficiencies constituted cost report fraud. Relator makes these allegations almost entirely on personal knowledge based on her insider status as a former participant in the PMSR program.

Earlier this year, in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016), the Supreme Court clarified the standard under the False Claims Act (“FCA”), holding that “the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions.” 136 S. Ct. at 1999. What matters for the FCA is

“whether the defendant knowingly violated a requirement that the defendants knows is material to the Government’s payment decision.” *Id.* at 1996. The allegations in the FAC—unsupervised and unpermitted residents, altered and falsified records, and absence of policies—were unquestionably relevant to the payment decision under Medicare and Medicaid. Moreover, the core of Relator’s complaint, that legally mandated supervision of the PMSR program at CIH was grossly inadequate or entirely lacking, is striking similar to the facts in *Escobar*.

As demonstrated in the FAC and below, Relator plausibly states claims under the Federal and State False Claims Acts, and sufficiently particularizes fraud under Fed. R. Civ. P. 9(b). Defendants’ motion to dismiss should therefore be denied.

### **FACTUAL BACKGROUND**

Relator is currently the Public Health Director in Fulton County, New York. She received her Doctorate in Podiatric Medicine in 2010, and is licensed to practice podiatry in New York. From July 2010 until late 2013, Relator was a graduate podiatric resident at CIH. While a resident, she had a limited residency permit authorizing her to practice podiatry in New York under the auspices of an approved GME program in podiatric medicine. Relator’s professional duties at CIH included consulting on patients at the outpatient podiatry clinic at CIH, assisting on surgical cases, and consulting on emergency room and inpatient podiatry patients at CIH. As a result of these patient interactions, Relator would regularly make entries into the medical records maintained by CIH for these patients. FAC at ¶ 6.

It was standard operating procedure for Defendants to bill Federal Health Care Programs for non-reimbursable teaching physician services and podiatry resident services. Billing would occur on a regular basis after Donovan entered a note in the medical record falsely indicating his oversight and involvement in patient care as an attending physician, and after Defendants

collected relevant charging information for each patient visit, including the specific services rendered and the associated billing codes. FAC at ¶¶ 52, 57, 62, 71, 76.

When Relator began her graduate podiatry training in the PMSR Program at CIH, she expected the CPME-approved Program would provide her with the training required to become a board-certified podiatrist and would otherwise comply with all of the standards and requirements of an approved residency program. Relator learned, however, that the PMSR Program at CIH not only failed to comply with most of the core requirements for maintaining CPME approval, but also that the Program operated unlawfully and in a fraudulent manner. FAC at ¶ 77.

#### **A. The Fraudulent Scheme to Conceal Material Defects in the PMSR Program**

##### **1. Lack of Faculty Supervision**

The FAC alleges an utter lack of faculty supervision of podiatric residents at CIH, which not only violated CPME Program Standard 6.0 *et seq.*, but also violated New York Educ. Law § 7008, requiring that podiatric residents function only “under the administrative supervision of a licensed podiatrist serving as the residency director.” FAC at ¶ 78.

Donovan was the only attending podiatrist in the PMSR Program to supervise all resident activities at CIH. In addition to being the PMSR Program Director, Donovan maintained a full-time private practice with office locations in Brooklyn and Manhattan. Relator regularly contacted Donovan to update him on patient interactions via text message, while Donovan was at his private office off-site of CIH, or at his Staten Island home. Donovan rarely attended inpatient podiatry consults, emergency room consults, or clinic consults in any capacity and did not regularly supervise the other residents in the PMSR Program. Although Donovan did make himself available to supervise surgical procedures performed by residents in the CIH operating rooms, many of those patients were referred through Donovan’s private practice. FAC at ¶ 79.

The complaint is replete with allegations that the residents were unsupervised, not merely that they were unsupervised by Donovan. *See, e.g.*, FAC at ¶¶ 53, 54, 58, 59, 63, 69, 74, 79, 80, 81, 82, 96, 102. The total abdication of supervisory responsibility of residents compromised the integrity of the PMSR Program and resulted in significant patient safety concerns.

For example, on August 9, 2010, Relator repaired a severely lacerated toe of a five-year-old girl in the Emergency Room of CIH entirely on her own, without any supervision. Similarly, on November 23, 2010, Relator repaired a severely lacerated flexor tendon of a 42-year-old male patient, again without supervision. Relator noted in both medical records that she “discussed findings, assessments and proposed recommendation with supervising attending,” which meant that she phoned and traded text messages with Donovan, while he was either in one of his off-site office locations or at his Staten Island home, after she had managed the care of the patient entirely on her own. FAC at ¶ 80.

A similar absence of faculty supervision occurred routinely at all levels of care of podiatry patients being treated within the PMSR Program at CIH, raising troubling patient safety issues and violating core CPME Program Standards mandating adequate faculty training resources and supervision (CPME Program Standards 5.5, 6.9). FAC at ¶ 81. Defendants’ failure to provide adequate faculty supervision seriously compromised the educational imperatives underlying the PMSR Program and mandated in CPME’s Program Standards, as well as the safety of podiatry patients at CIH.

## **2. Unauthorized Practice by PMSR Program Podiatrists**

An obvious minimum requirement for any GME program to be considered “approved,” including the PMSR Program at CIH, is that the residents participating in the program must be authorized under State law to practice their specialty—in this case podiatric medicine and

surgery—as a program participant. However, at least two graduate podiatry residents participated in the PMSR Program in the period between July 2010 and March 2012 without the limited residency permit required under New York Educ. Law § 7008.

Pursuant to section 7008, in order for an unlicensed resident to practice podiatry in a GME program, he or she must obtain a limited residency permit (“LRP”). Absent such a permit, a resident does not have legal authority to practice podiatry in New York and cannot render podiatric treatment or issue prescriptions to patients. Furthermore, practicing podiatry without legal authority, or aiding and abetting another individual to do so, is a Class E felony under New York Educ. Law § 6512. FAC at ¶ 65.

Neither Medicare nor Medicaid will pay for services furnished by practitioners who are not authorized by law to provide the services in question. Since residents may not participate in an approved residency program in New York State without a residency permit, services furnished by non-permitted residents are non-reimbursable under Medicare or Medicaid. FAC at ¶¶ 66-67. Nevertheless, when Relator was at CIH, Defendants allowed two podiatry residents in the PMSR Program to treat patients, write prescriptions and treat and perform surgeries without having a LRP and billed Federal Health Care Programs for those services. FAC at ¶¶ 71, 76..

Quinton P. Yeldell was not licensed as a podiatrist and did not have a valid LRP from July 1, 2011 until March of 2012. FAC at ¶ 68. Despite his lack of an LRP—and hence lack of any legal authority to practice podiatry in New York—Dr. Yeldell treated patients at CIH as a part of his residency training. FAC at ¶ 69. He wrote prescriptions and treated and performed surgeries on patients at CIH, on a daily basis, for a period of eight months, including numerous situations in which he was completely unsupervised, thereby deliberately circumventing New

York's licensing requirements and placing patients at risk. FAC at ¶ 69. Defendants did not terminate Dr. Yeldell from the PMSR Program until March 2012. FAC at ¶ 69.

Dr. Yeldell participated in at least the following surgical cases when he was unlicensed:

- (i) on September 9, 2011, he assisted on a bunionectomy/arthroplasty of the left foot of a 59-year-old female patient;
- (ii) on November 4, 2011, he assisted on a bone biopsy of the left foot of a 54-year-old male patient;
- (iii) on January 3, 2012, he assisted on a cyst removal of the right foot of a 23-year-old female patient;
- (iv) on January 1, 2012, he assisted on an arthroplasty of the left foot of a 58-year-old female patient; and
- (v) on January 26, 2012, he assisted on an arthroplasty of the fifth digit of a 35-year-old patient.

He also treated patients in the clinic, emergency room and on an inpatient basis during the same period. FAC at ¶ 70.

Michael Walters was not licensed as a podiatrist and did not have a valid LRP from July 30, 2010 to June 30, 2011. During this time, he treated patients and was even appointed by Donovan as the Chief Resident, supervising and teaching junior residents, and assuming more significant responsibilities in clinical matters. FAC at ¶ 72. Dr. Walters publicized on his LinkedIn.com profile that as Chief Resident—during the time when he was not licensed—his duties included: “Manage staff of four residents; Oversee daily clinic with an average of 60 patients; Performed over 300 surgical procedures; Treat ailments of the foot that include nail deformities, fractures and dislocations, bunion and hammertoe deformities, heel pain, sprains and strains, diabetic evaluation and treatment, gout, gait and biomechanical disorders. Research; Pharmaceutical lectures and training, Prescribing prescriptions.” FAC at ¶ 73.

Despite Dr. Walter's lack of legal authority to practice podiatry in New York, he wrote prescriptions and treated and performed surgeries on patients at CIH, on a daily basis, for eleven months, including situations when he was completely unsupervised, circumventing New York's

licensing requirements and placing patients at risk. FAC at ¶ 74. Dr. Walters graduated from the PMSR Program in June 2012. FAC at ¶ 74.

Dr. Walters participated in at least the following surgical cases when he was unlicensed: (i) on September 9, 2010, he assisted on an arthroplasty of the left foot of a 58-year-old female patient; (ii) on September 10, 2010, he assisted on a bunionectomy/arthroplasty of the right foot of a 59-year-old-female patient; and (iii) on November 18, 2010, he assisted on an arthroplasty of the left foot of a 46-year-old male patient. He also treated patients in the clinic, emergency room and on an inpatient basis during the same period. FAC at ¶ 75.

### **3. Creation of False Records**

Donovan also created and caused the creation of false entries in official PMSR Program records in order to fraudulently portray the Program as being in compliance with CPME requirements pertaining to the training of residents. FAC at ¶ 88.

Podiatry residents are required to keep track of their cases and patient interactions throughout their residency in order to document that they have met the necessary training requirements for graduation, as well as board certification eligibility. The PMSR Program utilizes an online data base called the Podiatry Residency Resource (“PRR”). Residents are required to enter their patient interactions into the PRR System, and the interactions are then supposed to be reviewed and verified by Donovan as the Program Director (CPME Program Standards 6.6, 7.1). If a resident does not attain the requisite number of surgical procedures, patient interactions, and other relevant competencies, the resident is not able to obtain a diploma and graduate from the PMSR Program. FAC at ¶¶ 89.

In 2012, CPME notified Donovan that, upon a review of records of Dr. Walters and his podiatry co-resident, there were deficiencies in Dr. Walters' patient encounters, particularly a lack of biomechanical examinations. FAC at ¶ 90.

In July and August of 2012, Donovan required Relator to reenter all of her cases into the PRR system as a result of alleged inaccuracies in her case logs. While reentering her cases, Relator discovered that a significant number of her cases had been verified by Donovan and transferred to other residents in the PMSR Program, even though those residents had not actually handled the cases at issue. For example, 17 biomechanical examinations performed and documented by Relator in the respective patient medical records maintained at CIH had been transferred by Donovan to Dr. Walters. In addition, another 39 procedures performed by Relator were given to other residents in the PMSR Program. FAC at ¶ 91.

Donovan was also falsifying records of PMSR residents who had already graduated from the Program in order to reflect their participation in clinical experiences that had not occurred. At the time, the PMSR Program at CIH was moving from a two-year to a three-year residency program, which would entail renewed scrutiny from CPME, and Donovan needed to ensure that the PMSR Program records could withstand such scrutiny and could demonstrate that there was a sufficient number of patient encounters to support the number of increased residency positions. The false PRR records concealed from CPME the defective training provided to podiatry residents in the PMSR Program. FAC at ¶¶ 91-92.

In a series of text messages, Dr. Walters discussed with Relator how Donovan had urged him to amend his PRR logs to add certain podiatry patient interactions called biomechanicals, that Donovan claimed were missing from the logs. Donovan had even gone so far as to coerce Dr. Walters' cooperation by raising the prospect of negating his second year of residency for lack

of a residency permit. Dr. Walters advised Relator that Donovan had threatened to “nullify” his second year of residency unless he rectified the situation involving his biomechanicals by amending the official record or returning to perform the procedures. Dr. Walters informed Relator that Donovan had contacted him about his PRR logs and requested that Dr. Walters come to meet Donovan, even though he was no longer in the Program. Donovan informed Dr. Walters that none of his biomechanicals were documented in the quadramed (electronic medical record system at CIH), and requested that Dr. Walters fill out a form for each of these patient records in order to meet the necessary graduation requirement of 75 biomechanical interactions, or return to the PMSR Program to perform the procedures. FAC at ¶ 93.

Donovan requested that Dr. Walters make entries for cases that Donovan fraudulently transferred from Relator to Dr. Walters, thereby hiding the fact that Dr. Walters should not have graduated the PMSR Program. The false entries also made it appear that there was a sufficient number of patient encounters to support the number of increased residency positions, had the program converted from two to three years. FAC at ¶ 94.

#### **4. Failure to Maintain Policies Governing the PMSR Program**

CPME also requires that the PMSR Program have a podiatry residency manual that includes policies and mechanisms affecting the resident, rules and regulations, curriculum, training schedule, assessments, a didactic activities schedule, and a journal review schedule (CPME Institutional Standard 3.10). CPME further requires that the residency manual be distributed to and acknowledged in writing by the resident at the beginning of the program (*Id.*). Relator and other residents in the PMSR Program did not receive podiatry-specific information of any kind earlier than May 2012, almost two years after Relator began her residency training,

and did not receive anything that could be considered a “manual” until after Relator complained about the lack of a PMSR manual to the CIH Human Resources Department. FAC at ¶ 85.

Notably, the information that was finally provided to Relator in May 2012 included a policy statement declaring that “Podiatry Residents cannot start their program without an official affidavit from NYS permitting resident to practice Podiatry in NYS.” Nevertheless, as described above, the PMSR Program either made no attempt to verify that its podiatry residents had obtained the necessary LRPs, or deliberately permitted non-permitted residents to participate in the Program and treat patients. Neither the PMSR program nor Dr. Donovan reported to CPME that podiatry residents were operating without LRPs. Moreover, the PMSR Program issued a graduate certificate to Dr. Walters even though he “graduated” the Program without having a LRP for almost his entire last year of training. FAC at ¶ 86.

CPME also mandates that the PMSR Program Director provide instructions to the residents on medical record keeping and on their entries to the residency case logs (CPME Program Standards 6.2, 6.6). At no time was Relator trained in record keeping matters related to podiatry and neither were the other residents in the PMSR Program. In addition, residents must receive formal evaluations at regular intervals (CPME Program Standard 7.2). Relator, however, never received a formal evaluation of her performance in podiatry assignments while she was a resident in the PMSR Program and, upon information and belief, the lack of a formal evaluation process was a standard operating procedure for the PMSR Program at CIH from at least July 1, 2010 to July 1, 2012. It was not until Relator complained about the lack of an evaluation process to the CIH Human Resources Department that the PMSR Program hurriedly instituted an evaluation process for residents in podiatry. FAC at ¶ 87.

### **5. Fraudulent Misrepresentations to CMS and CPME**

After CPME brought Relator's allegations concerning core deficiencies in the PMSR Program to the attention of CIH and asked CIH to respond, CIH responded to the allegations with additional fraudulent misrepresentations calculated to falsely reassure CPME and keep those deficiencies from coming to light. Among other things, CIH falsely represented, in response to Relator's complaint of inadequate faculty and supervision in the PMSR Program, that the podiatry division at CIH had "3 attendings on staff," when, in reality, Donovan was the only attending at CIH with any direct involvement in the PMSR Program and his supervisory functions outside the Operating Room were virtually non-existent. Other claims by CIH, including that Donovan was available to residents "24/7" and that he met with residents regularly and reviewed their logs monthly to ensure they were meeting the requirements of the PMSR Program, were also false. FAC at ¶ 96.

Nor were any of these deficiencies disclosed to the Centers for Medicare & Medicaid Services ("CMS") and the Medicare and Medicaid programs when Defendants submitted the costs associated with the PMSR Program for reimbursement year after year in CIH's cost reports. Those cost reports formed the sole basis on which Medicare and Medicaid made all DME and IME payments to CIH. However, Defendants concealed the fraud and misconduct that permeated the PMSR Program from CMS, as well as from CPME. Every annual cost report filed by CIH from in or about 2006 through at least in or about 2014 that claimed DME and IME costs associated with the PMSR Program without disclosing the fraud infecting the Program, or the fact that CIH was dishonestly maintaining the Program's "approved" status, constituted a false claim for GME funding. FAC at ¶ 97.

**B. The Fraudulent Scheme to Submit Claims for Non-Reimbursable Teaching Physician and Podiatry Resident Services**

**1. Outpatient Podiatry Clinic Claims**

As part of her resident duties, Relator saw patients at the CIH Outpatient Podiatry Clinic (“Clinic”). FAC at ¶ 46. During visits of 40-60 patients to the clinic each day, many of whom were covered under Medicare and Medicaid, the residents diagnosed patient conditions and performed podiatry-related procedures. These included nail and foot debridements, administering injections, treating foot conditions affecting diabetic patients and surgical procedures such as suturing lacerations, bone biopsies, skin biopsies, and skin graft/ matrix application, among other types of care. FAC at ¶ 47-48. The treatment of these patients was almost entirely conducted by Relator and the other residents. Donovan seldom attended Clinic patient visits or had any personal role whatsoever in the care of these patients. FAC at ¶ 48.

Notwithstanding Donovan’s complete lack of involvement in the care of these patients, and Federal Health Care Program reimbursement rules requiring his personal involvement, Defendants have billed the Federal Health Care Programs for Donovan’s services as if he were present for each patient visit and personally involved in the treatment rendered. FAC at ¶ 49. For example, on May 11, 2012, Relator personally treated seven patients, six of whom were covered by Medicaid, at the Clinic. Another podiatry resident was also treating patients. CIH electronic medical records show Donovan as the “Billing Prov” for Relator’s patients and includes an “Attndg Note” by Donovan entered on May 14, 2012. On May 11, Donovan attended a conference at Marriott Marquis and could not have been observing patients and supervising Relator. FAC at ¶ 50.

Moreover, Donovan’s notes are written as if he were present and supervising the treatment as the billing and attending physician, which is how he is described in the medical

records. Donovan's notes state that "the patient tolerated the visit well" and "tolerated LIDO/Steroid injection well for painful heal," falsely indicating that he was present for the patient encounter. FAC at ¶ 51.

The encounter notes for podiatry services provided by Relator and other podiatry residents were entered into the CIH electronic medical record system. After Donovan entered an attending note, and information on each patient visit, including the specific services rendered and the associated billing codes, was collected by Defendants, such services were billed to the Federal Health Programs. FAC at ¶ 52. Defendants' billing for Clinic patient visits that Donovan did not personally attend, and which were handled by unsupervised podiatry residents such as Relator, occurred on a regular basis. FAC at ¶ 54. As a result of Donovan's fabricated entries, Medicare and Medicaid were fraudulently billed for his professional services. Medicare and Medicaid also were fraudulently charged by Defendants for the unlicensed, unsupervised outpatient services of podiatry residents. FAC at ¶ 53.

## **2. Inpatient and Emergency Room Podiatry Claims**

As a podiatry resident, Relator and other podiatry residents also provided inpatient podiatric treatment and emergency room consults, with a significant number being covered by Medicare or Medicaid. FAC at ¶¶ 55, 60. As with the Clinic patients, Donovan seldom attended such inpatient visits or emergency room consults, or had any personal role in the care of these patients. FAC at ¶¶ 56, 61. The unsupervised podiatry residents in the PMSR Program diagnosed patients and performed podiatry-related procedures such as debridements, drainage of abscesses, and surgical procedures such as suturing lacerations, bone biopsies, skin biopsies, tendon repair, digit repair, metatarsal head resection, and skin graft/ matrix application, among other forms of treatment. FAC at ¶ 56. The unsupervised podiatry residents in the emergency

room diagnosed patients and performed invasive surgical procedures such as suturing lacerations, bone biopsies, skin biopsies, tendon repair, and digit repair, among other forms of treatment. FAC at ¶ 61.

As with the clinic notes, the podiatry residents' notes for inpatient and emergency room treatment were entered into the CIH electronic medical record system, Donovan entered an attending note and information on the specific services rendered and the associated billing codes. These services were then billed to the Federal Health Programs. FAC at ¶¶ 57, 62.

Despite a complete lack of supervision in the care of these patients, and Federal Health Care Program reimbursement rules requiring personal involvement, Defendants have billed the Federal Health Care Programs for Donovan's services as if he had been personally involved, and Medicare and Medicaid also were fraudulently charged for the unlicensed, unsupervised inpatient services of podiatry residents. FAC at ¶¶ 58-59, 63-64.

### **3. Claims Based on Treatment by Legally Unauthorized Residents**

As stated above, Dr. Yeldell and Dr. Walters both participated in the PMSR Program, for eight months and eleven months respectively, during which time they treated patients on a daily basis, without having the requisite LRP. FAC at ¶ 83.

Incredibly, in the case of Dr. Walters, during his final year of residency training (from July 30, 2010 through June 30, 2011), he was named the Chief Podiatry Resident, and yet he did not even have the LRP required to lawfully practice podiatry during that period. The Chief Podiatry Resident is a highly significant and responsible position within the PMSR Program. According to a PMSR Program policy regarding the responsibilities of the Chief Podiatry Resident, provided to Relator on May 9, 2012 by CIH personnel, the Chief Resident's

responsibilities include, "...the supervision of all the podiatry residents and serves as a liaison between the program director and the resident staff." FAC at ¶ 84.

Defendants submitted charges to Medicare and Medicaid indicating Donovan as the attending physician, based on treatment and surgeries performed by Dr. Yeldell and Dr. Walters in the PMSR Program, notwithstanding the fact that neither held the required LRP to practice podiatry as a resident in New York State. Since the services performed were not lawfully rendered by a resident as required for reimbursement, all amounts charged and paid for such services are fraudulent. FAC at ¶¶ 71, 76.

## **ARGUMENT**

### **Point I**

#### **STANDARDS FOR A MOTION TO DISMISS**

##### **A. A Complaint Must State A Claim That Is Plausible**

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Facial plausibility" is achieved when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556); see *Turkmen v. Hasty*, 789 F.3d 218, 240 (2d Cir. 2015) (plaintiffs "need not prove their allegations; they must *plausibly plead* them."). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679; see *Harris v. Mills*, 572 F.3d 66, 71 (2d Cir. 2009) ("We consider the legal sufficiency of the complaint,

taking its factual allegations to be true and drawing all reasonable inferences in the plaintiff's favor.”).<sup>1</sup>

### **B. False Claims Act Liability**

As the Second Circuit explained in *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001), *abrogated on other grounds*, *Universal Health Services, Inc. v. U.S. ex. rel. Escobar*, 136 S. Ct. 1989 (2016) “to impose liability under the [False Claims] Act [Plaintiff] must show that defendants: (1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury.” A claim can be “legally false” by misrepresenting compliance with a particular statute, regulation or contract term, or it can be “factually false” by incorrectly describing the goods or services provided or requesting reimbursement for goods or services that were never provided. *Id.* at 696-97. Further, as the Supreme Court recently held in *Escobar*, 136 S. Ct. at 1999, 2002, **both** fraudulent misrepresentations and omissions of material of fact are actionable under the FCA, provided that they are material to the government’s payment decision.

### **C. Pleading Fraud With Particularity Under Fed. R. Civ. P. 9(b)**

In a case alleging fraud under the False Claims Act, Relator must satisfy the heightened pleading standard of Rule 9(b), which requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” *Wood ex rel. U.S. v. Applied Research Associates, Inc.*, 328 Fed.Appx. 744, 747 (2009). The Second Circuit has recognized that the “primary purpose of Rule 9(b) is to afford defendant fair notice of the plaintiff’s claim and the factual ground upon which it is based.” *Ross v. Bolton*, 904 F.2d 819, 824 (2d Cir. 1990). “Rule 9(b) also safeguards defendant’s reputation and goodwill from

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<sup>1</sup> Relator agrees that a New York State False Claims Act claim may not be maintained against HHC because it is not a “person” under the New York State FCA. Def. Mem. at 39-40. A claim against HHC may properly be maintained under the Federal False Claims Act.

improvident charges of wrongdoing . . . and it serves to inhibit the institution of strike suits.” *Id.* (citations omitted).

However, the Second Circuit has expressly noted, in applying Rule 9(b), “the general rule that pleadings are to be construed in the light most favorable to the pleader and accepted as true . . . and not be dismissed, unless it appears that plaintiff can prove no set of facts that would entitle him to relief . . . is not thereby abrogated.” *Id.* Rather, “when fraud is asserted, the general rule is simply applied in light of Rule 9(b)’s particularity requirements.” *Id.* (citations omitted).

## Point II

### **RELATOR PLAUSIBLY ALLEGES CLAIMS UNDER THE FALSE CLAIMS ACT**

#### **A. The Supreme Court’s *Escobar* Decision Demonstrates That Relator’s Allegations Describing The Submission Of Claims For The Services Of Unsupervised, Unpermitted Residents Without Disclosing The Failure To Comply With Basic Regulatory Requirements Mandating That Such Services Be Professionally Supervised And Legally Authorized State Valid Claims Under The FCA.**

The strength and validity of Relator’s FCA claims are well-illustrated by the Supreme Court’s recent landmark decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016). *Escobar* arose out of care rendered to a female teenage Medicaid beneficiary at Arbour Counseling Services, a mental health center in Massachusetts owned and operated by Universal Health Services, Inc. The teenager died of a seizure in 2009 at age 17, while still under Arbour’s care. The *qui tam* complaint alleged that she had been treated by assorted unqualified and unsupervised counselors, in violation of various staffing and licensing regulations governing the Massachusetts Medicaid program (known as MassHealth).<sup>2</sup> The complaint further alleged

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<sup>2</sup> Specifically, the *Escobar* relators alleged that after their child’s death, they learned from an Arbour staff member that “that few Arbour employees were actually licensed to provide mental health counseling and that supervision of them was minimal.” *Escobar*, 136 S. Ct. at 1997. Moreover, relators discovered, among other things, that “[r]ather than ensuring supervision of unlicensed staff, the clinic’s director helped to misrepresent the staff’s qualifications” and that “[s]ome 23 Arbour employees lacked licenses to provide mental health services, yet—despite regulatory requirements to the contrary—they counseled patients and prescribed drugs without supervision.” *Id.*

that compliance with such regulations was a condition of payment by MassHealth and that Arbour's Medicaid claim submissions, which did not disclose its failure to comply with the regulations, thus were false under the Federal and State False Claims Acts.

The First Circuit Court of Appeals framed the issue as being “simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment.” *United States ex rel. Escobar v. Universal Health Services*, 780 F.3d 504, 512 (1st Cir. 2015). The First Circuit answered that question in the affirmative, after first noting that “[p]reconditions of payment, which may be found in sources such as statutes, regulations and contracts, need not be ‘expressly designated.’” *Id.* (citation omitted). The First Circuit held that the regulatory provisions at issue “clearly impose[d] conditions of payment,” that those provisions require “*appropriate supervision*” and that “*the core of Relators’ complaint*” was that “*supervision at Arbour was either grossly inadequate or entirely lacking.*” *Id.* at 513-14 (emphasis added). The court also found that the Relators sufficiently pleaded: (1) that Arbour's claims were false since they “*misrepresented compliance with a condition of payment, i.e., proper supervision*”; (2) that “the condition of payment at issue was a material one”; and (3) that “Arbour knowingly submitted false claims to MassHealth” by alleging facts establishing “that Arbour acted in reckless disregard or deliberate ignorance of the falsity of the information contained in the claims.” *Id.* at 515. (emphasis added). The court concluded that “each time it submitted a claim, Arbour *implicitly communicated* that it had conformed to the relevant program requirements, such that it was entitled to payment.” *Id.* at 512, 514 n.14 (emphasis added) (citation omitted).

In a unanimous decision, the Supreme Court agreed that *implied false certification* was a

valid theory of recovery under the FCA, reasoning that “by punishing defendants who submit misrepresentations, the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions,” and that when a defendant “makes representations in submitting a claim but omits its violations of statutory, regulatory or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided,” and those misrepresentations are material to the government’s decision to pay the claim. *Escobar*, 136 S. Ct. at 1999, 2001-02.

The Supreme Court declined to recognize artificial distinctions between “conditions of payment” and “conditions of participation,” and rejected any requirement that a regulation be expressly designated a “condition of payment,” finding such a designation to be “relevant” but not dispositive of whether a defendant’s failure to disclose its noncompliance with the regulation was “material” to the government’s payment decision. *Id.* at 1996, 2001-02. As stated in *Escobar*, “[w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.” *Id.* at 1996. Under the FCA, “materiality means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,” and *Escobar* affirmed that concept while also clarifying that “[u]nder any understanding of the concept, materiality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.’” *Id.*, at 20032 (citation omitted). Knowledge of materiality, moreover, will be imputed if “a reasonable person would realize” the materiality of a particular requirement and the defendant’s failure to do so amounted to “deliberate ignorance” or “reckless disregard” under the FCA. *Id.* at 2001.

As applied to the facts in *Escobar*, the Supreme Court noted that “the Massachusetts Medicaid program requires satellite facilities to have specific types of clinicians on staff, *delineates licensing requirements for particular positions (like psychiatrists, social workers, and nurses), and details supervision requirements for other staff.*” *Id.* at 1998 (emphasis added). The Court held that Arbour’s claims to the Medicaid program amounted to actionable “half-truths” by representing that Arbour had provided certain specific counseling services through particular staff members without also disclosing that Arbour had committed “*many violations of basic staff and licensing requirements*” mandated by MassHealth and that these omissions rendered the claims “misrepresentations” under the FCA. *Id.* at 2000-2001 (emphasis added). The Court continued, “*By using payment and other codes that conveyed this information without disclosing Arbour’s many violations of basic staff and licensing requirements for mental health facilities, Universal Health’s claims constituted misrepresentations.*” *Id.* at 2000 (emphasis added). The Court ultimately concluded that Arbour had “misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations.” *Id.* at 2004. The analysis in *Escobar* is controlling in this case.

Strikingly similar to the facts in *Escobar*, the FAC in this case alleges that patients seeking podiatry services—including surgical services performed outside the operating room in outpatient, inpatient and emergency room settings—were treated by unsupervised and unlicensed residents enrolled in the PMSR program at CIH. Also similar to *Escobar*, the regulations governing Medicare and Medicaid required that these residents-in-training—who lacked any State license permitting them to independently practice podiatry and treat patients without the

oversight of another licensed podiatrist as part of a bona fide graduate medical education program—be *supervised* in order for their services to be reimbursable.

As alleged in the FAC, however, that essential supervision was non-existent at CIH. Unlicensed residents performed all manner of medical services on patients without any supervision whatsoever, including “debridements, drainage of abscesses, and surgical procedures such as suturing lacerations, bone biopsies, skin biopsies, tendon repair, digit repair, metatarsal head resection, and skin graft/ matrix application, among other forms of treatment.” FAC, ¶¶ 48, 56, 61, 73, 75. In the case of two PMSR residents, including one who (incredibly) had received the designation “Chief Resident,” the residents lacked even a valid residency permit under State law, meaning they could not lawfully participate in the PMSR program at all. FAC at ¶¶ 65-76.

As alleged in the FAC, Defendants fraudulently induced Medicare and Medicaid to pay for these unlicensed, unsupervised PMSR resident services in a number of different ways.

For services performed on outpatients, Defendants billed and caused the billing of teaching physician services in the name of Donovan by misrepresenting his supervisory involvement in the services performed by the residents and without disclosing that the residents performed those services entirely on their own, thus making the services non-reimbursable under teaching physician billing guidelines, not to mention imperiling the safety of the patients who received those services. Similarly, Defendants billed and caused the billing of hospital services for outpatients that incorporated professional services rendered by unlicensed, unsupervised residents, all without disclosing their non-compliance with regulations barring payment for resident services that were entirely unsupervised and that, as a consequence, posed a profound safety risks to CIH patients. FAC at ¶¶ 46-76.

For services performed on inpatients, resident services were paid with funding received from Medicare and Medicaid for graduate medical education. Defendants applied for such funding on an annual basis through the submission of cost reports to the government detailing CIH's direct and indirect graduate medical education costs. FAC at ¶¶ 38-42. However, as alleged in the FAC, those cost reports were materially misleading because they did not disclose the fraud permeating the PMSR program at CIH, including, among other things, the total absence of resident supervision that was a core GME requirement. FAC at ¶¶ 77-97. Accordingly, Defendants' submission of those cost reports for the purpose of inducing Medicare and Medicaid funding for unsupervised resident services rendered to inpatients constituted cost report fraud under the FCA.

As in *Escobar*, in billing and accepting reimbursement for these outpatient and inpatient services, Defendants implicitly (and falsely) represented that they had satisfied the fundamental supervision requirements for residents in the PMSR program that were a condition of payment, both as a matter of explicit regulatory language and as a matter of common sense. Billing and claiming reimbursement for the costs associated with these services without disclosing to government payers the total absence of resident supervision was plainly a misrepresentation material to the government's payment decision and a false claim under the FCA. To paraphrase *Escobar*, the supervision of unlicensed residents-in-training is "so central to the provision of" medical services (and protecting patients), that Medicare and Medicaid clearly "would not have paid these claims had it known of these violations." *Escobar*, 136 S.Ct. at 2004.

**B. Resident Supervision Is A Condition Of Payment Under The Medicare And Medicaid Programs for Teaching Physician and Hospital Services**

As alleged in the FAC, regardless of whether the medical and surgical services of an unlicensed resident-in-training are incorporated into a payment request by a teaching physician

who involves residents in the care of his or her patients, or whether those services are part of a payment request for hospital services rendered to patients within the scope of an approved medical education program, physician supervision of the resident is a condition of payment. FAC at ¶¶ 29-45. The complaint is replete with allegations that the residents were “unsupervised,” not merely that they were unsupervised by Donovan. *See, e.g.*, FAC at ¶¶ 53, 54, 58, 59, 63, 69, 74, 79, 80, 81, 82, 96, 102.

### **1. Teaching Physician Services**

Medicare regulations explicitly require that a teaching physician billing for services performed by a resident-in-training be “physically present during the critical or key portions of the service.” CMS Fact Sheet, “Guidelines for Teaching Physicians, Interns and Residents” at p. 1; see 42 C.F.R. §§ 415.170, 415.172, 415.174. When a resident visits a patient without the teaching physician being present, the teaching physician must repeat the key portions of the visit and have his or her own documentation in order to get paid. Medicare Benefit Policy Manual (“MBPM”), Chapter 15, 30.2. 31. Importantly, since the PMSR residents in this case performed assorted surgical services (*see* FAC at ¶¶ 48, 56, 61, 73, 75), such services are reimbursable only if the teaching physician is physically present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. 42 C.F.R. § 415.172(a)(1). To qualify teaching physician claims for reimbursement, moreover, the medical record must contain signed or countersigned notes by the physician proving that the physician personally reviewed the patient's diagnoses, visited the patient at critical times of the illness, and discharged the patient. MBPM, Chapter 15, 30.2. For surgical procedures, there must be notes in the record by interns, residents, or nurses, indicating that the attending physician was physically present when the service was rendered. *Id.* In addition, the teaching physician must be identified

as such on the claims by including a GC modifier for each service to indicate: "This service has been performed in part by a resident under the direction of a teaching physician." MBPM, Chapter 12, 100.1-100.2; CMS Fact Sheet, "Guidelines for Teaching Physicians, Interns and Residents." By including the GC modifier, the provider is certifying that he or she has complied with the requirements for billing such services. *Id.*

As alleged in the FAC, here Defendants knowingly billed and caused the billing of Medicare for the teaching physician services of Donovan where he had no personal involvement in the services that were rendered, which were instead performed by podiatry residents-in-training without any professional supervision whatsoever. FAC at ¶¶ 46-64. Moreover, two of the residents for extended periods lacked valid residency permits, and hence had no legal authority, to participate in the PMSR program at all, and thus their services could never have supported the billing of teaching physician services, even if the requirements for such billing were satisfied (which they were not). FAC at ¶¶ 65-76.

Medicaid regulations governing the billing of teaching physician services are consistent with Medicare requirements, but as Defendants acknowledge (Mem. of Law, at pp. 9-10), Medicaid differs from Medicare by not defining "physician" to include the services of a podiatrist or permitting podiatrists to bill their services separately to Medicaid when such services are rendered in a hospital setting. *See* 42 U.S.C. §§ 1395x(r)(1); 1396d(a)(5); New York State Medicaid Update, March 2010, Volume 26, Number 4. Those services are instead bundled into a Medicaid claim for hospital services incorporating the professional services of all non-physician practitioners, including podiatrists. Here, as discussed below, those services were rendered, not by a licensed podiatrist whose services might have been legitimately bundled into a

claim for hospital services and reimbursed on that basis, but rather by unlicensed, unsupervised podiatry residents. Such services were non-reimbursable.

## 2. Hospital Services

Both Medicare and Medicaid will pay for hospital services that incorporate patient care services performed by residents-in-training in certain circumstances.

In the case of Medicare, the professional services of residents rendered within the scope of an approved training program are paid in the form of direct and indirect graduate medical education payments. *See* 42 U.S.C. § 1395ww(h); 42 C.F.R. §§ 412.2(f)(7); 412.105, 413.75 *et seq.*, 419.2(c)(1). As discussed below, the supervision of unlicensed residents in the PMSR program at CIH was a core requirement for program approval and Medicare funding. The absence of such supervision in the PMSR program, among other core program deficiencies and fraudulent practices that were concealed from the government in CIH's annual cost reports and from the PMSR program's accrediting body, the Council on Podiatric Medical Education ("CPME"), rendered false and fraudulent CIH's annual requests for GME funding.

Nor was CIH entitled to bill Medicare for the professional services of residents under the "incident-to" regulations governing hospital outpatient services. *See* 42 C.F.R. § 410.27. The express terms of that regulation state that "Medicare Part B pays" only for hospital outpatient services that are provided "incident to" a physician's services under that physician's "direct supervision." *Id.* at § 410.27(a)(1)(ii), (iv). Under the regulation, residents are *not* "non-physician practitioners" who can supervise their own services. *Id.* at § 410.27(a)(1)(iv)(C), (g).

As alleged in the FAC, the PMSR residents at CIH treated patients entirely unsupervised, with no other physician involved in the patients' care. Thus, the residents' services were not merely an "incidental part of a physician's" services, nor were they operating under "direct supervision" of a physician who was "immediately available to furnish assistance and direction

throughout the performance of the procedure,” as the regulations required. *Id.* at 410.27(a)(1)(ii), (iv)(A). Furthermore, two of the residents lacked valid residency permits that would entitle them to participate in the PMSR program and render medical services to patients. Accordingly, CIH’s submission of claims to Medicare for podiatry outpatient services that incorporated the “incident to” services of unlicensed PMSR residents, without disclosing that such services were wholly unsupervised and did not involve the participation of a licensed physician in any respect, was false and fraudulent under the FCA.

Although Medicaid pays for "personal and identifiable services ... by the ... resident with oversight by the attending physician to the Medicaid patient" in an inpatient setting, as noted above, Medicaid does not define podiatrists as "physicians" and thus supervision of podiatry residents by licensed podiatrists—even if that had occurred (which it did not)—would not have satisfied the terms of these Medicaid inpatient policy guidelines. Medicaid Inpatient Policy Guidelines, at p. 10 (November 21, 2012).

In outpatient settings, Medicaid pays for medical services, including podiatry services, which may be bundled into a claim for hospital services and reimbursed under Medicaid’s Ambulatory Patient Group (“APG”) rates,<sup>3</sup> but Medicaid requires that such services be provided by a licensed health care professional in accordance with DOH regulations. "Medical services" are defined as the "services of physicians, nurse practitioners, licensed practical nurses, registered nurses, registered physician's assistants and *other health care professionals licensed and certified by the Education Department to*" treat patients (emphasis added). New York State Medicaid Program, Policy Guidelines for Article 28 Certified Clinics, at p. 39. Further, in providing medical services, a hospital outpatient department "must comply with all applicable

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<sup>3</sup> See New York Department of Health, “Policy and Billing Guidance Ambulatory Patient Groups (APGs),” Revision 2.1 (August 2012); 10 NYCRR § 86-8.1 *et seq.*

provisions of State law." *Id.* at p. 39. When billing Medicaid for services provided by a hospital outpatient department, the claim "must be consistent with the scope of practice, certification and/or profession of the rendering provider," who must be a "qualified licensed practitioner." *Id.* at p. 5. Unlicensed podiatry residents, not to mention unlicensed and unpermitted residents who are not even entitled under State law to treat patients as participants in a graduate medical education program, plainly do not meet these requirements, and their services thus are non-reimbursable under Medicaid.

It further bears emphasis that "[r]esidents and interns (even if licensed) do not function independently" in the outpatient clinic setting and "should only provide medical care under appropriate supervision." New York State Medicaid Update, June 2009, Volume 25, Number 7; *see also* 10 NYCRR § 405.4(f)(3)(ii), (iv)(b), (c) (imposing hospital requirement of "continuously monitoring" patient care services provided by [residents] to assure provision of quality patient care services within the scope of privileges granted" and requiring preoperative and postoperative "examination and assessment" of all surgical patients by "attending physicians"). These plainly are fundamental regulatory requirements intended to assure patient safety in the context of resident training programs.

Therefore, all professional services furnished by unlicensed, unsupervised and/or unpermitted residents-in-training who participated in the PMSR program at CIH, whether provided in an inpatient or outpatient setting, and whether billed as an individual claim for professional services or bundled into a more comprehensive claim for hospital services, were non-reimbursable under the Medicaid program. All Medicaid claims submitted by CIH for hospital services that incorporated the professional services of podiatry residents in the PMSR program, without disclosing the unlicensed, unsupervised and/or unpermitted nature of those

services, were false and fraudulent under the FCA. The only Medicaid funding that could have been available for lawful PMSR resident activities—if supervision requirements had been satisfied (which they were not)—would have taken the form of direct and indirect GME payments.

**C. Residents Were Required To Have Limited Residency Permits  
For Services To Be Reimbursible Under Medicare And Medicaid**

Defendants do not dispute that in order for an unlicensed resident to practice podiatry under the auspices of a GME program, he or she must obtain a limited residency permit (“LRP”) pursuant to New York Educ. Law § 7008; that absent such a permit, a resident is without legal authority to practice podiatry, render podiatric treatment or issue prescriptions; and that practicing podiatry without legal authority is a Class E felony under New York Educ. Law § 6512. *See supra* at 5; FAC at ¶ 65.

Defendants nevertheless argue that a podiatry resident’s failure to have an LRP is not material to the Medicare and Medicaid payment decision. Def. Mem. at 31-37. This argument should be rejected based upon the Supreme Court’s decision in *Escobar*. In that case, the provider’s claims amounted to actionable “half-truths” where they represented that they had provided counseling services without disclosing “many violations of basic staff and licensing requirements.” 136 S. Ct. at 2000-2001. The Court concluded the provider had “misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations.” *Id.* at 2004.

The FAC alleges that two residents—each without an LRP for a substantial period of time—participated in the PSMR Program, treating patients, writing prescriptions, and treating and performing surgeries. It is difficult to imagine how the fact that unlicensed and unpermitted

podiatry residents were allowed to treat patients would not be material to the Medicare and Medicaid payment decision.

Neither Medicare nor Medicaid will pay for services furnished by practitioners who are not authorized by law to provide the services in question. As relevant here, Medicare defines a resident as “one who is formally accepted, enrolled, and participating in an approved medical residency program, including programs in . . . podiatry, as required in order to become certified by the appropriate specialty board.” 42 C.F.R. § 413.75(b). Since residents may not participate in an approved residency program in New York State without a residency permit, services furnished by non-permitted residents are non-reimbursable under Medicare.

Medicaid similarly will only pay for services “provided by qualified . . . practitioners within the scope of their practice as defined by State law” and will not pay for services which are “professionally unacceptable” as, for example, practicing a profession “fraudulently beyond its authorized scope” or rendering care while “one’s license to practice is suspended or revoked.” New York State Medicaid Program, Information for All Providers, General Policy, pp. 7, 23-24. In addition, all Medicaid claims carry a Claim Certification Statement by the provider that all care and services were rendered in compliance with federal and state laws and regulations, as well as all DOH policies. New York State Medicaid Program, Information for All Providers, General Billing, pp. 7-8. Since residents may not provide care or services under State law if they do not possess a valid residency permit, services furnished by non-permitted residents are non-reimbursable under Medicaid.

**D. Submission Of Cost Reports While Concealing The Alleged Fraudulent Activities In The PMSR Program At CIH Were False Claims Material To A Payment Decision By Medicare And Medicaid**

Medicare and Medicaid contribute funds to pay the costs associated with approved graduate medical education ("GME") programs. Medicare pays for both direct ("DME") and

indirect ("IME") costs of GME programs. *See* 42 U.S.C. § 1395ww(h); 42 C.F.R. §§ 412.2(f)(7); 412.105, 413.75 *et seq.*, 419.2(c)(1). Under Medicaid, States may elect in their plans to provide additional funding for GME programs, subject to approval by CMS. The New York Medicaid Program provides such additional funding for GME programs, which is added as a component to a hospital's inpatient rates. New York State funds this program with general budget appropriations through the New York Department of Health. As with Medicare, the New York Medicaid Program funds both the DME and IME costs of GME. 10 NYCRR § 86-1.20.

Payments for DME, among other things, help cover the costs incurred by hospitals for medical residents and teaching faculty, including salaries, fringe benefits, and allocations of overhead. Calculation of Medicare's share of the DME amount is obtained by multiplying the number of Full-Time Resident Equivalents by the authorized per-resident amount and then multiplying that result by the hospital's Medicare patient load. 42 C.F.R. §§ 413.76, 413.77. These Medicare amounts are calculated and paid based on information included in the hospital's cost report. Calculation of Medicaid's share of the DME amount in New York is likewise based on the hospital's cost report and determined as set forth in the New York Public Health Law and related regulations. New York Public Health Law § 2807-c; 10 NYCRR Part 86.

Payments for IME are intended to cover the additional incremental costs associated with the more intensive care, treatment and increased availability of state of the art testing technologies found in teaching hospitals and related to the training of residents. Calculation of Medicare's share of the IME amount is based on information included in the hospital's cost report and utilizes a complex formula established by regulation. 42 C.F.R. § 412.105. As with DME, calculation of Medicaid's share of the IME amount in New York is based on the hospital's cost

report and determined as set forth in the New York Public Health Law and related regulations.

New York Public Health Law § 2807-c; 10 NYCRR Part 86.

Under Medicare, the hospital cost reports incorporating GME-related costs are submitted on a CMS-approved form that contains both an advisory and a certification of truth and accuracy.

The advisory states:

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL CIVIL AND ADMINISTRATIVE ACTION, AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

Immediately below this advisory is a certification which states:

I HEREBY CERTIFY that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by [the hospital] for [the relevant cost reporting period] and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of [the hospital] in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

FORM CMS-2552-10 (Hospital Cost Report Form); 42 USC 1395g; 42 C.F.R. § 413.20(b).

Medicaid Institutional Cost Reports contain similar certifications.

In order to be reimbursable, GME costs, like all costs, must be “reasonable,” meaning that they must be actually incurred and “necessary for the efficient delivery of the service.” 42 C.F.R. §§ 413.13(a); 413.30(a)(2); *see also* 10 NYCRR § 86-1.6(a), (d), (e). Additionally,

hospitals must have approved graduate medical education programs to qualify for DME and IME payments under the Medicare and Medicaid programs. In the field of podiatric medicine, an "approved" program is a residency program approved by the Council on Podiatric Medical Education ("CPME") of the American Podiatric Medical Association ("APMA"). 42 C.F.R. §§ 413.75(b), 415.152. Among the many core standards and requirements published by CPME, with which a podiatric residency program must comply in order to achieve and maintain approved status, is the requirement that residents receive "*appropriate faculty supervision during all training experiences.*" CPME, "Standards and Requirements for Approval of Residencies in Podiatric Medicine and Surgery" at § 6.9 (emphasis added). Moreover, the PMSR Program Director has a non-delegable duty to assure appropriate resident supervision and faculty members "*must supervise and evaluate the resident in clinical sessions and assume responsibility for the quality of care provided by the resident during the clinical sessions that they supervise.*" *Id.* at §§ 5.3, 5.5 (emphasis added).

Here, the FAC alleges that in order to maintain the "approved" status of the PMSR program, and continue to receive federal funding from Medicare and Medicaid for direct and indirect GME costs associated with the program, Defendants misrepresented resident credentials and concealed material facts that would have revealed the fraudulent nature of the program, causing Medicare and Medicaid to deny GME funding. The FAC includes specific allegations concerning the fraudulent nature of the PMSR program:

- Relator and other residents were permitted to perform procedures on patients without supervision by Donovan;
- At least two graduate podiatry residents were not properly licensed, including one who was named Chief Podiatry Resident;
- The program had numerous training and policy deficiencies;

- Defendants transferred a number of Relator's cases in the CIH electronic medical records to other residents in the PMSR program, so it would appear as if the other residents had handled the cases, even though they had not;
- Defendants fraudulently inflated clinical patient encounters attributed to some residents in order to enable those residents to fraudulently graduate from the program;
- Defendants altered medical records to create the false impression that residents had attained certain clinical competencies; and
- Defendants allowed residents to perform surgical procedures on patients without a residency permit or license.

A graduate medical education program that lacks any faculty supervision of residents in outpatient, inpatient and emergency room settings; allows unlicensed residents to perform medical and surgical procedures on patients without faculty oversight and, in the case of two residents who lacked residency permits, without any legal authority; and falsifies clinical records in order to misrepresent resident competencies, among many other critical defects described in the FAC (§§ 77-97), is no medical education program at all. There can be no question that such deficiencies would be material to a Medicare or Medicaid payment decision. *See Escobar*, 136 S. Ct. at 2000-01, 2004. A program that fraudulently conceals such deficiencies cannot be deemed "approved" for purposes of Medicare and Medicaid. Furthermore, by submitting annual cost reports to Medicare and Medicaid seeking reimbursement of PMSR-related GME costs without disclosing these core program deficiencies, all of which were plainly material to CMS's decision to fund CIH's PMSR program and reimburse those GME costs as "reasonable," CIH repeatedly made false claims that violated the FCA.

The PMSR Program at CIH could not have maintained its approved status if CMS and CPME had known of such blatant misconduct, in addition to all the other critical violations of core CPME Institutional and Program Standards described above. Certainly, a podiatric medicine and surgery residency program that tolerates such practices cannot be said to be

“established and conducted in an ethical manner” (CPME Institutional Standard 3.12). However, Defendants’ misconduct was never reported by Defendants to CPME pursuant to PMSR Program requirements mandating that CPME be notified regarding “the conduct of” and “substantive changes to” the Program (CPME Institutional Standards 4.0-4.2). FAC at ¶ 95.

Defendants argue that the PMSR Program continued to be approved by CPME, and that is the end of the inquiry. Def. Mem. at 37-39. This ignores the allegation that CPME was misled, FAC at ¶ 96, and ignores the fact that the fraudulent nature of the program also was a fraud on CMS. In *U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78 (2d Cir. 2012), the Second Circuit addressed misrepresentations as to the key personnel contributing to a federally funded grant program. The Court determined defendants were liable because the government had lost the opportunity to award grant money to a recipient who would have used the money as the government intended. With respect to materiality, the Court held that the test under the FCA is objective, determining whether the proven falsehoods have a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. The Court held that the trial evidence was more than sufficient for a jury to conclude that the true facts would have had a natural tendency to influence the decision on the grant renewal. 697 F.3d at 96; *see U.S. ex rel. Miller v. Weston Educ., Inc.*, 2016 WL 6125551 (8<sup>th</sup> Cir. Oct. 19, 2016).

Here, the PMSR Program at CIH was a fraud on Medicare and Medicaid. Defendants’ argument, taken to its logical progression, would mean that as long as CPME has not withdrawn a Program’s approval, a PMSR Program could have unsupervised and unpermitted residents performing medical and surgical procedures, fraudulently alter medical and training records, and have the numerous other core training and policy deficiencies described above, and its submission of cost reports generating funding for the PMSR Program would not constitute false

claims. This cannot be correct. The allegations of the FAC are more than sufficient to plausibly state a claim that knowledge of the true facts concerning the PMSR Program at CIH would have been material, as they would have had a natural tendency to influence the payment decision. *Escobar*, 136 S. Ct. at 2000-01, 2004; *Feldman*, 697 F.3d at 96.<sup>4</sup>

### Point III

#### **RELATOR HAS SUFFICIENTLY PLED FRAUD UNDER RULE 9(b)**

As stated above, FCA fraud allegations must be pled with specificity. While Rule 9(b) generally requires a complaint to “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Applied Research Associates, Inc.*, 328 Fed.Appx. at 747 (citing *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994)), “every element of the who, what, where, why and when of the fraud does not need to be pled with utmost detail so long as the scheme of fraud itself is specifically and particularly pled.” *Pullman v. Alpha Media Publishing, Inc.*, 2013 WL 1290409, at \*14 (S.D.N.Y. 2103). Although at least some claim details must be alleged, “no one detail is mandatory” and “there is no per se rule that an FCA complaint must provide exact billing data or attach a representative sample claim” provided that the allegations in the complaint provide some “indicia of reliability” that false claims were actually submitted. *U.S. ex rel. Mastej v. Health Management Associates*, 591 Fed. Appx. 693, 704 (11th Cir. 2014), *cert. denied*, 135 S. Ct. 2379 (2015); *accord U.S. ex rel. Bilotta*

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<sup>4</sup> The cases relied upon by Defendants (Def. Mem. at 39) are inapposite because they pre-date *Escobar* and are factually distinguishable, dealing with circumstances where certification of an organization was not required for reimbursement, *U.S. ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F.Supp.2d 8, 20 (D.D.C. 2003), and the distinction between conditions of payment and participation, *U.S. ex rel. Qazi v. Bushwick United Housing Devel. Fund Corp.*, 977 F. Supp. 2d 235, 240-41 (E.D.N.Y. 2013). Neither case deals with the types of fraud alleged in the FAC, which permeated the PMSR program at CIH.

*v. Novartis Pharmaceuticals Corp.*, 50 F.Supp.3d 497, 510 (S.D.N.Y. 2014); *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318, 336 (D. Conn. 2004).

Courts have expressly held that such “indicia of reliability” may be supplied by the personal knowledge allegations of “a relator with direct, first-hand knowledge of the defendants’ submission of false claims gained through [his] employment with the defendants [and who] may have a sufficient basis for asserting that the defendants actually submitted false claims.” *Mastej*, 591 Fed. Appx. at 707. In *U.S. v. Huron Consulting Group, Inc.*, 2011 WL 253259 (S.D.N.Y. Jan. 24, 2011), the Court applied the reasoning of these cases, holding that allegations of the existence of a billing scheme and particular and reliable indicia that false bills were submitted were sufficient to satisfy Rule 9(b). *Id.* at \*2 (citing *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009)).<sup>5</sup> *Accord U.S. ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 918 (8<sup>th</sup> Cir. 2014) (sufficient indicia of reliability where a plaintiff pleads details of defendant’s billing practices and personal knowledge of the submission of false claims); *Liberty Mutual Fire Ins. Co. v. Acute Care Chiropractic Clinic P.A.*, 2015 WL 632187, at \*12 (Feb. 13, 2015 D. Minn.) (citing *Thayer* for proposition that personal knowledge of false claim submissions and detailed allegations of billing practices can supply indicia of reliability); *U.S. ex rel. Schaengold v. Memorial Health, Inc.*, 2014 WL 7272598, at \*16 (Dec. 18, 2014 S.D. Ga.) (“Relator can provide sufficient indicia of reliability if he alleges personal knowledge regarding the submission of claims.”); *U.S. ex rel. Dittman v. Adventist Health System/Sunbelt, Inc.*, 2013 WL 615820 at \*1 (Feb. 19, 2013 M.D. Fla.) (allegations had indicia of reliability where relator set forth factual basis for personal knowledge).

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<sup>5</sup> Defendants cite district court cases applying a stricter rule, suggesting that specific individual claim information must be alleged, even if relator alleges reliable indicia of false bills and such information is in the exclusive possession of defendant. *See* Def. Mem. at 17-21. However, “there is no published Second Circuit decision addressing this issue.” *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 253 (S.D.N.Y. 2014). Relator submits the Court should follow the reasoning of the cases cited above under the facts of this case.

In addition, the heightened pleading requirements of Rule 9(b) will be relaxed to permit allegations on “information and belief” when, for example, “the necessary evidence of the essential elements of the claim is within the exclusive control of the defendant” or “the fraud being alleged is part of a complex scheme occurring over a long period of time” or involving “numerous occurrences.” *U.S. ex rel. Ellis v. Sheikh*, 583 F.Supp.2d 434, 438-39 (W.D.N.Y. 2008) (citations omitted); *Accord Applied Research Associates, Inc.*, 328 Fed.Appx. at 747 (interpreting prior holding in *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990) and recognizing that Rule 9(b) may be relaxed to permit “information and belief” allegations where the complaint alleges “specific facts supporting a strong inference of fraud”); *DiVittorio v. Equidyne Extractive Indus.*, 822 F.2d 1242, 1247 (2d Cir. 1987) (exception to information and belief pleading under Rule 9(b) exists when facts are “peculiarly within the opposing party's knowledge” and facts on which belief is based are alleged); *Segal v. Gordon*, 467 F.2d 602, 608 (2d Cir. 1972) (same); *U.S. ex rel. Mooney v. Americare, Inc.*, 2013 WL 1346022, at \*3 (E.D.N.Y. 2013) (“Courts in this Circuit have ... relaxed the pleading requirement ‘in cases involving complex fraudulent schemes or those occurring over a lengthy period of time....’ ” (quoting *U.S. ex rel. Tiesinga v. Dianon Sys., Inc.*, 231 F.R.D. 122, 123 (D. Conn. 2005))); *United States v. Bank of New York Mellon*, 941 F.Supp.2d 438, 481–82 (S.D.N.Y. 2013) (recognizing that “in setting forth a ‘complex and far-reaching scheme’ the government need allege only ‘representative samples’ of fraudulent conduct to satisfy Rule 9(b).”) (citation omitted).

Further, where it is alleged that a fraudulent practice was institutionalized throughout an organization, courts will not insist on details concerning the specific individuals within the organization who perpetrated the scheme. *See U.S. ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112,

125 (D.C. Cir. 2015) (“[A]lleging with specificity how the company itself institutionalized and enforced its fraudulent scheme, and how it was manifested in corporate training materials and audit reports, sufficiently identifies who committed the fraud for the purposes of Rule 9(b). [If] [t]he complaint makes clear, in other words, that corporate levers were pulled; identifying precisely who pulled them is not an inexorable requirement of Rule 9(b) in all cases.”)

As part of her PMSR Program training, Relator was instructed in the necessity of adequate and complete record keeping so that patient care services could be properly billed. The standard operating procedure was for Relator and other residents to enter encounter notes for their services into the CIH electronic medical record system to be reviewed and/or amended by Donovan. After Donovan entered an attending note, and information on each patient visit, including the specific services rendered and the associated billing codes, was collected by Defendants, the services were billed to the Federal Health Care Programs. FAC at ¶ 50-52, 57, 62, 71, 76. The FAC specifically alleges that Donovan was described as the “Billing Prov[ider]” on medical records, and that he supplied his “Attending Note.” FAC at ¶ 50.

With respect to GME, Defendants do not dispute that they applied for such funding on an annual basis through the submission of cost reports to the government detailing CIH’s direct and indirect graduate medical education costs. However, as described above, those cost reports were materially misleading because they did not disclose the fraud permeating the PMSR program at CIH, including, among other things, the total absence of resident supervision that was a core GME requirement. Defendants’ submission of those cost reports to induce Medicare and Medicaid funding for unsupervised resident services rendered to inpatients constituted cost report fraud under the FCA.

Relator in this case was an “insider” podiatry resident with first-hand knowledge of CIH’s record systems and its procedures for the billing of services, supplying the “indicia of reliability” that false claims were submitted by Defendants. *See Mastej*, 591 Fed. Appx. at 707. In addition, the specific claim information is “within the exclusive control of the defendant,” and “the fraud being alleged is part of a complex scheme occurring over a long period of time” and involving “numerous occurrences.” *See Ellis*, 583 F.Supp.2d at 438-39. Moreover, the fraudulent practice alleged in the FAC was institutionalized throughout CIH. *See Heath*, 791 F.3d at 125.

It bears emphasis, moreover, that Defendants effectively corroborated Relator’s billing and GME fraud allegations by retaliating against Relator in her employment for raising her well-founded compliance concerns with CIH’s Human Resources Department. FAC at ¶¶ 98-106. Relator describes in detail how she came to know that Defendants had committed Medicare and Medicaid fraud and how CIH and Donovan made her suffer for the integrity she displayed in reporting these findings to her employer. These allegations, like all other allegations in the FAC, must be accepted as true for purposes of this motion to dismiss. *Harris v. Mills*, 572 F.3d at 71. The fact that Defendants punished Relator for bringing her compliance concerns to their attention certainly tends to enhance the plausibility and reliability of her allegations.

The allegations of the FAC sufficiently and particularly allege fraud under Fed. R. Civ. P. 9(b), and the motion to dismiss should be denied on that ground.

#### **Point IV**

#### **IF THE COURT FINDS DEFICIENCIES IN THE FIRST AMENDED COMPLAINT, IT SHOULD GRANT RELATOR LEAVE TO REPLEAD**

In the event the Court finds that Relator’s allegations are deficient in some way, she should be granted leave to replead, particularly since the FCA standard has been recently

clarified by the Supreme Court in *Escobar*. “Complaints dismissed under Rule 9(b) are ‘almost always’ dismissed with leave to amend.” *Luce v. Edelstein*, 802 F.2d 49, 57 (2d Cir. 1986). In *Luce*, the Second Circuit held that the dismissal of the complaint without granting leave to amend was an abuse of discretion. *Id.* at 57-58; *see also Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 54-55 (2d Cir.1995) (“Leave to amend should be freely granted, especially where dismissal of the complaint [is] based on Rule 9(b)”).

### **CONCLUSION**

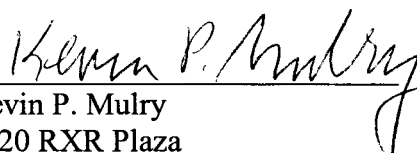
For all of the foregoing reasons, the Court should deny the Defendants’ motion to dismiss the First Amended Complaint.

Dated: New York, New York  
October 21, 2016

Respectfully Submitted,

FARRELL FRITZ, P.C.

By:

  
Kevin P. Mulry  
1320 RXR Plaza  
Uniondale, New York 11556-1320  
Tel. (516) 227-0620

KAISER LAW FIRM, PLLC  
Geoffrey R. Kaiser  
926 RXR Plaza  
Uniondale, New York 11556-0926  
Tel. (516) 570-3071

WEISS, ZARETT, BROFMAN &  
SONNENKLAR, P.C.  
David A. Zarett  
3333 New Hyde Park Rd., Suite 211  
New Hyde Park, New York 11042  
Tel: (516) 627-7000